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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,289	09/18/2003	Madaline Chirica	DX01074B	8664

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,289	CHIRICA ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 27-31* is/are rejected.

7)☒ Claim(s) *25 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/18/03 & 7/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for the withdrawal of the restriction requirement filed 8/15/2006 is acknowledged. Applicant requests the withdrawal based on the preliminary amendments filed 9/18/2003. Therefore, Office will withdraw the restriction requirement of 5/15/2006. Claims 24-31 are pending and are examined.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. Applicant is required to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

4. The IDS submitted 9/18/2003 and 7/28/2005 have been considered.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated or cultured cell comprising an expression vector, does not reasonably provide enablement for a host cell comprising an expression vector. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Examiner has interpreted the claims 28 and 29 as reading on isolated host cells, as well as host cells intended for gene therapy. The specification discloses "gene therapy may render desired cell populations response to p40/IL-B30 ligand, e.g., as adjuvants for tumor immunotherapy, to facilitate activation of tumor infiltrating lymphocytes, T cells, or NK cells" (page 40). However, the specification does not teach any methods or working examples that indicate DCRS5 nucleic acid is introduced and expressed in a cell for therapeutic purposes. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. For example, the specification does not teach what type of vector would introduce the DCRS5 nucleic acid into the cell or in what quantity and

duration. Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene therapy is to deliver DNA to the target tissues and to transport it to the cell nucleus to enable the required protein to be expressed (Phillips, A.; pg 1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length of time (pg 1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express DCRS5 nucleic acid into the cell of an organism. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to introduce and express DCRS5 nucleic acid in the cell of an organism or be able to produce DCRS5 protein in that cell.

Due to the large quantity of experimentation necessary to introduce and express DCRS5 nucleic acid in a cell of an organism for therapy, the lack of direction/guidance presented in the specification regarding how to introduce DCRS5 nucleic acid in the cell of an organism to be able to produce DCRS5, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of transferring genes into an organism's cells, and the breadth of the claims which fail to recite any cell type limitations, undue experimentation

would be required of the skilled artisan to make and/or use the claimed invention in its full scope. (Please note that this issue could be overcome by amending the claims to recite, for example, "An isolated host cell...").

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 31 is rejected as being vague and indefinite in the recitation of the term "IL12Rβ1 polypeptide". Abbreviations and acronyms should be spelled out at their first use in the claims for clarity. The protein of interest is described by an arbitrary abbreviation. It is unclear from which species the nucleic acid encoding the said protein was isolated. Applicant should particularly point out and distinctly claim the IL12Rβ1 by claiming structural characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is.

6b. Claim 31 is rejected as vague and indefinite because it is unclear what is the composition of kit? Further, it is unclear if the compartment or kit comprises the nucleic acid of claim 24 or if the claim is directed to a collection of elements with a kit as one element and compartments as separate elements. In addition, the recitation of "or" after

part (b) and before part(c) makes the claim not further limiting because part (c) only provides for instructions and this encompasses a "kit" which has the nucleic acid and instructions for use, which does not distinguish over just the nucleic acid alone.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7a. Claim 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Mahairas et al. (1999).

Claims are drawn to isolated nucleic acids. The claims recite the phrases "an isolated polynucleotide" and " an antigenic polypeptide " and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 1-2, including sequences only 13 nucleic acids or 8 amino acids in length (see specification pages 5 and page 16).

Mahairas et al. (1999). discloses polynucleotide encoding an antigenic polypeptide of SEQ ID NO: 2 (see Appendix A1-2). Thus, the reference anticipates the polynucleotide encoding an antigenic polypeptide of SEQ ID NO: 2. Therefore, claim 24 is rejected as being anticipated by Mahairas et al. (1999). However, this rejection

maybe obviated by Applicant rewriting the claim as follows "An isolated or recombinant polynucleotide encoding the polypeptide of SEQ ID NO: 2".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahairas et al. (1999) in view of Delcuve (U.S. Patent No. 5, 888, 774).

The teachings of Mahairas et al. has been disclosed above in paragraph 8a. However, the teachings do not disclose vector, host cells, methods of making the polypeptide and kits.

Delcuve disclose vectors (column 9, lines 59-65), mammalian host cells (column 10, lines 5-20) and methods of making the polypeptide (column 11, lines 56-59). They also disclose the use of kits (column 19, lines 17-35). It would have been *prima facie* obvious at the time of the invention to insert the DNA disclosed in Mahairas et al. into vectors and host cells taught by Delcuve. One of ordinary skill in the art would have been motivated to insert the DNA disclosed in Mahairas et al. into the vectors and mammalian host cells disclosed in Delcuve to express the polypeptide because the Delcuve teaches the preparation of recombinant protein by transfecting the mammalian cell with an expression vector to produce the protein of interest (column 4, line 28-35). Further, there is reasonable expectation of success because inserting DNA into vectors for expression in mammalian host cells for the expression of protein is routine in the art. In addition, it is also routine to include polynucleotides in kit (column 19, lines 17-35). Therefore, the instant invention is *prima facie* obvious over over Mahairas et al. (1999) in view of Delcuve (U.S. Patent No. 5, 888, 774).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chirica et al. (U. S. Patent No. 6, 756, 481) disclose antibodies binding to SEQ ID NO: 2 of the instant invention. The instant Application is a DIV of the previously allowed patent.

10. Claims 25 and 26 will be allowable if written independent of rejected claim 24.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647,
October 25, 2006

Gegeetheesan Sahu Segar
Patent Examiner